



K012486

JAN 16 2002

510(k) Summary

Device Proprietary Name: OsteoMed Bioresorbable Fixation System

Device Common Name: Plating System

Classification Name: HRS, Plate, Fixation, Bone

Name of Submitter: OsteoMed Corporation
3750 Realty Road
Addison, Texas 75001
Phone: (972) 241-3401
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Contact Person: Dawn T. Holdeman

Date Prepared: July 31, 2001

Summary:

This submission describes the OsteoMed Bioresorbable Fixation System indicated for use in trauma and reconstructive procedures in the midface and craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas, comminuted fractures of the frontal sinus wall and midfacial fractures, and reconstructive procedures of the midface or craniofacial skeleton. This system is not intended for use in the mandible and/or full load bearing procedures.

The OsteoMed Bioresorbable Fixation System is comprised of various plates, meshes and screws. Plates and meshes, 0.5mm through 1.2mm thick, are provided in various shapes and sizes. Screws are provided in 1.6mm diameter in lengths of 4.0mm through 8.0mm. Safety screws are 2.0mm diameter in lengths of 4.0mm through 8.0mm. The implanted components of the device are manufactured from 70:30 poly L/D,L-lactide.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Macropore Protective Sheet (K972913), the Synthes Resorbable Fixation System (K974554) and the Stryker Leibinger Resorbable Fixation System (K993061).

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Bioresorbable Fixation System does not raise any new safety or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2002

Ms. Dawn T. Holdeman
Regulatory Affairs and Document Control
OsteoMed Corporation
3750 Realty Road
Addison, Texas 75001-4311

Re: K012486
Trade/Device Name: OsteoMed Bioresorbable Fixation Sytem
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: November 26, 2001
Received: November 27, 2001

Dear Ms. Holdeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

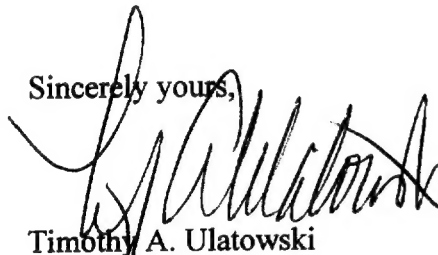
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OsteoMed "Indications for Use" Submission

510(k) Number:

K012486

Device Name:	OsteoMed Bioresorbable Fixation System
Indications for Use:	<p>Indicated for use in trauma and reconstructive procedures in the midface and craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas, comminuted fractures of the frontal sinus wall and midfacial fractures, and reconstructive procedures of the midface or craniofacial skeleton.</p> <p>The OsteoMed Bioresorbable Fixation System is not intended for use in and is contraindicated for: the mandible and/or full load bearing procedures; in cases of active or suspected infection or in patients who are immunocompromised; in cases where there is limitation of the blood supply or inadequate volume or quality of bone to place the system securely; in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation.</p>

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 810.109)

Over-The Counter-Use _____
(Optical Format 1-)

Susan Rivera

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012486